1642

NOV 0 1 2004 THANKING

Dkt. 0575/61136/JPW/AJM/AJD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Andrew R. Marks and Steven O. Marx

NOV 08 2004

U.S. Serial No.:

09/766,944

Examiner: A.M. Harris

Filed:

January 22, 2001

Art Unit: 1642

TECH CENTER 1600/1960

For:

P27 PREVENTS CELLULAR MIGRATION

1185 Avenue of the Americas New York, New York 10036

October 27, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

This Supplemental Information Disclosure Statement is submitted under 37 C.F.R. §1.97(c)(2) to supplement the Information Disclosure Statements filed April 20, 2001 and May 24, 2002 in connection with the above-identified application.

In accordance with their duty of disclosure under 37 C.F.R., §1.56, applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (Exhibit A), and attached hereto as Exhibits 1-11:

- 1. U.S. Patent No. 6,177,272 B1, issued January 23, 2001 to Nabel et al. (Exhibit 1);
- 2. PCT International Publication No. WO 91/02140, published February 1, 1996 (Exhibit 2);
- 3. Braun-Dullaeus et al. (1997) Regulation of vascular smooth muscle cell proliferation by the cyclin-dependent kinase inhibitor p27^{KIP1}. J. Invest. Med. 45(3): 224A (Exhibit 3);
- 4. Chen, D. et al. (1997) Downregulation of cyclin-dependent kinase 2 activity and cyclin A promoter activity in

Applicants: Andrew R. Marks and Steven O. Marx

Serial No.: 09/766,944

Filed: January 22, 2001

Page 2

vascular smooth muscle cells by $p27^{KIP1}$, and inhibitor of neointima formation in the rat carotid artery. J. Clin. Invest. 99(10): 2334-2341 (Exhibit 4);

- 5. Hirai, A. et al. (1997) Geranylgeranylated rho small GTPase(s) are essential for the degradation of p27^{Kip1} and facilitate the progression from G1 to S phase in growth-stimulated rat FRTL-5 cells. J. Biol. Chem. 272(1): 13-16 (Exhibit 5);
- 6. Kawamata, S. et al. (1998) The upregulation of p27 by rapamycin results in G1 arrest in exponentially growing T-cell lines. Blood 91(2): 561-569 (Exhibit 6);
- 7. McArthur, J. G. (1999) Cancer gene therapy with novel chimeric p27/p16 tumor suppressor genes. Proceedings of the Annual Meeting of the American Association for Cancer Research 40: 630 (Exhibit 7);
- 8. Sun, J. et al. (1999) Rapamycin inhibits vascular endothelial cell proliferation via induction of a cyclin-dependent kinase inhibitor. J. Am. Coll. Cardiol. 33(2): 250A-251A (Exhibit 8);
- 9. Tanaka, T. et al. (1998) Activation of cyclin-dependent kinase 2 (Cdk2) in growth stimulated rat astrocytes: geranylgeranylated rho small GTPase(s) are essential for the induction of cyclin E gene expression. J. Biol. Chem. 273(41): 26772-26778 (Exhibit 9);
- 10. Tanner, F.C. et al. (1998) Expression of cyclin-dependent kinase inhibitors in vascular disease. Circ. Res. 82(3): 396-403 (Exhibit 10); and

Applicants: Andrew R. Marks and Steven O. Marx

Serial No.: 09/766,944

Filed: January 22, 2001

Page 3

11. Tanner, F.C. et al. (1997) Gene transfer of $p27^{K1P2}$ and $p21^{CIP1}$ cyclin-dependent kinase inhibitors, but not $p16^{INK}$, negatively regulate VSMC proliferation through differential effects on kinase activity. Circulation 96(8): 15 (Exhibit 11).

The Examiner is respectfully requested to make these references of record in the present application by initialing and returning a copy of the enclosed Form PTO-1449.

Applicants note that the above-listed references were previously cited in an International Search Report or in a Supplementary Partial European Search Report issued in connection with foreign counterparts of the subject application. A copy of the International Search Report is attached hereto as Exhibit B, and a copy of the Supplementary Partial European Search Report is attached hereto as Exhibit C.

Applicants also note that the second reference (WO 99/03508) cited in the July 23, 2004 International Search Report (Exhibit B) is not listed above because this reference was previously made of record in the subject application, having been cited to the Examiner in the Supplemental Information Disclosure Statement filed May 24, 2002. Similarly, the Luo et al. (1996) and Gallo et al. (1999) references cited in the September 29, 2004 Supplementary Partial European Search Report (Exhibit C) are not listed herein because they were previously disclosed in the Information Disclosure Statement filed April 20, 2001 in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

Applicants:

Andrew R. Marks and Steven O. Marx

Serial No.:

09/766,944

Filed:

January 22, 2001

Page 4

Pursuant to 37 C.F.R. §1.97(c)(2) and 1.17(p), a fee of one hundred and eighty dollars (\$180.00) is required for filing this Supplemental Information Disclosure Statement. Accordingly, a check in the amount of ONE HUNDRED EIGHTY DOLLARS (\$180.00) is enclosed. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

.

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Commissioner for Patents
P.O Box 1450, Alexandria, VA 22313-1450

Alan I Morrison

Alan J. Morrison Reg. No. 37,399 27/07

Date

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

Sheet 1 of 1

TECH CENTER 1600/2900 Atty. Docket No. Serial No. Form F 61136/JPW/AJM/AJD 09/766,944 U.S. Department of Commerce Patent and Trademark Office Applicant(s) Andrew R. Marks and Steven O. Marx ON DISCLOSURE CITATION Filing Date Group Art Unit several sheets if necessary) January 22, 2001 1642 U.S. PATENT DOCUMENTS Exh. Examiner **Document Number** Date Name Class Subclass Filing Date Initials No. If Appropriate 1 6 7 2 2 01/23/01 Nabel et al. FOREIGN PATENT DOCUMENTS Translation **Document Number** Date Country Class Subclass Yes No 2 9 2 02/01/96 0 0 **PCT** OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Braun-Dullaeus et al. (1997) Regulation of vascular smooth muscle cell proliferation by the cyclin-dependent kinase inhibitor p27^{KIP1}. J. Invest. Med. 45(3): 224A; Chen, D. et al. (1997) Downregulation of cyclin-dependent kinase 2 activity and cyclin A 4 promoter activity in vascular smooth muscle cells by p27^{KIP1}, and inhibitor of neointima formation in the rat carotid artery. J. Clin. Invest. 99(10): 2334-2341 Hirai, A. et al. (1997) Geranylgeranylated rho small GTPase(s) are essential for the degradation of p27^{Kip1} and facilitate the progression from G1 to S phase in growthstimulated rat FRTL-5 cells. J. Biol. Chem. 272(1): 13-16; Kawamata, S. et al. (1998) The upregulation of p27 by rapamycin results in G1 arrest in exponentially growing T-cell lines. Blood 91(2): 561-569; McArthur, J. G. (1999) Cancer gene therapy with novel chimeric p27/p16 tumor suppressor genes. Proceedings of the Annual Meeting of the American Association for Cancer Research 40: 630; Sun, J. et al. (1999) Rapamycin inhibits vascular endothelial cell proliferation via induction of a cyclin-dependent kinase inhibitor. J. Am. Coll. Cardiol. 33(2): 250A-251A; 9 _ Tanaka, T. et al. (1998) Activation of cyclin-dependent kinase 2 (Cdk2) in growth stimulated rat astrocytes: geranylgeranylated rho small GTPase(s) are essential for the induction of cyclin E gene expression. J. Biol. Chem. 273(41): 26772-26778; 10 Tanner, F.C. et al. (1998) Expression of cyclin-dependent kinase inhibitors in vascular disease. Circ. Res. 82(3): 396-403; and Tanner, F.C. et al. (1997) Gene transfer of p27^{K1P2} and p21^{CIP1} cyclin-dependent kinase inhibitors, but not p16^{INK}, negatively regulate VSMC proliferation through differential effects on kinase activity. Circulation 96(8): 15. 11/ **EXAMINER** DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through

citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicants: Andrew R. Marks and Steven

O. Marx

Serial No: 09/766.944 Filed: January 22, 2001

Exhibit A